DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

May 6, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 – 20

Steve L. Denk
President
Barr Animal Foods
A Division of Barr Enterprises, Inc.
W7276 Chickadee Road
Greenwood, Wisconsin 54437

Dear Mr. Denk:

On April 8, 2003, an investigator from the Food and Drug Administration (FDA) inspected your rendering and animal feed manufacturing operation located at W7276 Chickadee Road, Greenwood, WI. This inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000, "Animal Proteins Prohibited in Ruminant Feed" (21 CFR 589.2000). The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Under 21 CFR 589.2000(g)(2), such deviations cause products being manufactured and/or distributed by this facility to be deemed misbranded within the meaning of Section 403(a)(1) of the Federal Food, Drug and Cosmetic Act (the Act), and these products may not be lawfully introduced, or delivered for introduction, into interstate commerce.

Products that contain or may contain protein derived from mammalian tissues and are intended for use in animal feed must be labeled with the cautionary statement, "Do not feed to cattle or other ruminants." This is required by 21 CFR 589.2000(c)(1)(i). The FDA suggests the statement be distinguished by different type size or color, or other means of highlighting the statement so that it is easily noticed by a purchaser. Our inspection found that you are not labeling your 50-pound blocks of frozen beef and bulk loads of beef bone chips and rendering waste, which are intended for animal feed, with that caution statement. As a result, these products are misbranded within the meaning of Section 403(a)(1) of the Act.

The above is not intended to be an all-inclusive list of deviations from the regulations. As a renderer and manufacturer of materials intended for animal feed use, you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide Nos. 67 and 68 to assist you with complying with the regulation.

You should take prompt action to correct these violations and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

It is necessary for you to take action on this matter now. Please provide this office a written response within 15 working days of receipt of this letter with the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be taken within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,

David R. Foster
for W. Charles Becoat
Director
Minneapolis District

TGP/ccl

Enclosures: Small Entity Compliance Guides no. 67 and 68